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09/589,675	06/07/2000	Steven C. Murray	PA1513US	8651

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EXAMINER

FARAH, AHMED M

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 06/16/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/589,675

Applicant(s)

Murray et al.

Examiner

First Last

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1234



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 20, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 13
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 9, 14, 15, 17-27, 30, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Sinofsky (U.S. Patent No. 4,852,567).

As to claims 1-3, 9, 17, 22-24, 27, 30, and 33, Sinofsky discloses tissue irradiation devices and methods of use for delivering treatment energy towards a target tissue, the devices comprising:

a fluorescent element {laser crystal 32 (see Col. 4, lines 40-55 and Col. 5, lines 29-41)} positioned to receive pump radiation having a narrow spectral band {radiation from pump laser 12 inherently has a narrow spectral band (see Fig. 1 and Col. 5, lines 42-45)} and responsively generate emitted radiation 30, the emitted radiation being diffuse and having a peak emission outside the narrow spectral band of the pump laser {in one embodiment, the emitted radiation, which has a peak emission outside the pump radiation, is a diffused radiation (see Fig. 4 and Col. 7, lines 11-14)}.

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As to claims 14, 18, 19-21, 25, and 26, Sinofsky uses optical waveguide having a core and cladding to direct the radiation. Furthermore, his waveguide comprises reflectors/redirectors coated with dielectric material to direct at least a portion of the emitted radiation towards the tissue being treated (see Col. 4, lines 56-58; and Col. 5, lines 18-28). As to claim 15, the distal end of his device is configured to contact the target tissue.

In this Office Action (OA), the term fluorescence is treated as *'the emission of electromagnetic radiation that is caused by the flow of some form of energy to the emitting body and which ceases abruptly when the excitation ceases'*. The fluorescent spectra is defined as the *'emission spectra of fluorescence in which an atom or molecule is excited by absorbing light and then emits light of characteristic frequency.'*

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-12, 14, 17-30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jegorov et al. in view of Sinofsky (U.S. Patent No. 6,270,492 B1) and in view of Byren et al. (U.S. Patent No. 4,853,528).

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As to claim 1 and 33, Jegorov et al. disclose a device for irradiating biological tissue, the device comprising: a pump radiation source (pump laser 10) for generating exciting radiation; an optical waveguide (optical fiber 3) coupled to the radiation source; a fluorescent element (laser crystal 6) positioned to receive pump radiation having a narrow spectral band (i.e., 1.12  $\mu\text{m}$ ) and to responsively generate emitted radiation, the emitted radiation having a peak emission (i.e., 3  $\mu\text{m} \pm 0.2 \mu\text{m}$ ) that is outside the narrow spectral band of the pump source; and a redirector (laser converter 2 comprising protective coating and mirror surfaces 7 and 8) for directing the emitted radiation toward a tissue site.

As to claim 17, the redirector (laser converter 2) includes a reflective entrance face (coupling optic 5) and reflective walls (see Fig. 1), the entrance face having an aperture that admits pump radiation into the redirector.

As to claims 18-21, Jegorov et al., described above, use waveguide/optical fiber to direct the treatment light to the tissue site. Hence, optical fibers inherently comprise reflective walls having a boundary between a waveguide core with a relatively high index of refraction and a cladding material having a relatively low index of refraction. Furthermore, coating the reflective walls with a metallic and/or dielectric coating is known in the art.

As to claims 22-26, their device would inherently provide the method steps as presently claimed.

As to claims 27-30, their device is configured for the treatment of biological substance in stomatologic, endoscopic, dermatological, and the like procedures.

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However, Jegorov et al. fail to teach the use of a light diffusing device as presently claimed. As to claims 4-8 and 11, Although Jegorov et al. disclose a fluorescent material, they do not particularly teach the use of liquid dyes or solid medium consisting of polymer as the active medium for fluorescing the incident radiation.

Sinofsky ('492 B1) teaches a photo-therapeutic apparatus comprising a light-diffusing fiber tip assembly (10) having a radiation scattering particles (24) selected from a group consisting of a polymer, glass or suitable liquids (see Col. 9, lines 27-33). However, although Sinofsky teaches the use liquids fluorescent medium, he does not particularly teach the use of liquid dyes.

As known in the art of non-linear optics, Byren teaches the use of nonlinear optical mediums (i.e., solid, liquid, or gas), which can be used for shifting light frequency. In one embodiment, he uses fluorescent dye as a frequency shifter.

Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Jegorov et al. in view of Sinofsky and in view of Byren to have an alternative frequency shifting means (such as a polymer or liquid dyes) in order to select a wavelength suitable for a particular/desired treatment. It would have been further obvious to one skilled in the art, at the time of the applicant's invention to modify Jegorov et al. with Sinofsky and use a diffuse light in order to provide larger exposure area for phototherapy. The diffused light would further alleviate or reduce the problems that inherently result from contact of tissue with a catheter device that provides a coherent and/or focused light during the treatment process.

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5. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jegorov et al. in view of Sinofsky ('492 B1) and Byren et al. and in further view of Talpalriu et al. U.S. Patent No. 6,171,302 B1.

Jegorov et al., described above, do not teach that the incident radiation is delivered to the handpiece through an articulated arm.

However, Talpalriu teaches an alternative treatment apparatus and method for delivering therapeutic light to patient's skin. Fig. 2 of Talpalriu teach that the incident radiation is delivered to the handpiece through an articulated arm.

Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Jegorov et al. with Talpalriu and use optical fiber or an articulated arm as an alternative light guide~~y~~ in order to deliver energy from external light source to handpiece for irradiating tissue.

6. Claims 15, 16, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jegorov et al. in view of Sinofsky ('492 B1) and Byren et al. and in further view of Braun et al. (U.S. Patent No. 5,425,754).

Although Jegorov et al., described above, disclose a transparent window with a proximal face positioned adjacent to the fluorescent element, they fail to teach a means for cooling the window and the distal end of their window is not configured to contact the target tissue.

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However, Braun et al. disclose an alternative method and device for irradiating tissues, the device comprising: a radiation source (lamp 8) for emitting a treatment light; a reflector (7), which directs the incident light toward the treatment site; a cuvette (4) consisting of casing (9) and two transparent "windows" (10), which are normal to the optical path of the incident radiation; and water (11) deposited inside the cuvette for cooling the target tissues. Thus it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Jegorov et al. with Braun et al. and have a tissue cooling window that is disposed between the irradiation source and the target site in order to cool the tissues, and to control and keep the temperature of the tissues at a desired level.

### *Conclusion*

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,



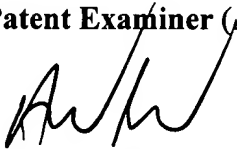
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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703) 305-5787. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can be reached on (703) 308-0994. The official fax number for the group is (703) 872-9302; and the fax number for After Final is (703) 872-9303.

**A. M. Farah**

**Patent Examiner (Art Unit 3739)**

  
June 12, 2003

  
**Linda C. M. Dvorak**

**Supervisory Patent Examiner**